K121429

AUG 10 2012

5 510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Information:

Submitter name:	**Aïmago SA** Parc Scientifique EPFL PSE-D, 4th floor 1015 Lausanne, Switzerland
Contact person during review:	Marc André
Contact Title:	Chief Technology Officer
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Submission Type:	Traditional 510(k)
Date prepared:	08 May 2012

Device Name:

Proprietary name:	Aïmago EasyLDI
Common name:	Laser Doppler Imager
Class	Class II
Classification name:	21 CFR 870.2120, Extravascular blood flow probe
Product code:	DPT
Review panel:	Cardiovascular

Predicate Device:

Substantial Equivalence is claimed with the predicate devices:

- moorLDLS Laser Doppler Line Scanner (K063561), and the
- moorLDI2-IR Infrared Laser Doppler Imager (K032841)

both manufactured by MOOR INSTRUMENTS LTD., Millwey, Axminster, Devon (UK).

Both the new and the predicate devices use the Laser Doppler imaging technology to visualize blood flow in the microcirculation. While the predicate devices perform a single point and a 1-dimensilonal line scan, respectively, the Aïmago EasyLDI performs a 2-dimensional area scan.

Device Description:

The Aïmago EasyLDI microcirculation camera is a device for imaging blood flow in the microcirculation. It uses the established laser Doppler technique to quantify movement of blood cells beneath the skin surface. Unlike the predicate devices, the EasyLDI performs a 2-dimensional Laser Doppler area scan to build up a color coded image of blood flow more rapidly than either predicate device. The moorLDLS laser Doppler line scanner uses a line scanner to sweep a line of laser light across the tissue to build up the image of blood flow and the moorLDI2-IR laser Doppler imager uses a single low power infrared laser beam to achieve this goal.

Intended Use:

The Aïmago EasyLDI microcirculation camera is intended for blood flow measurements in the microcirculation.

Comparison of Technological Characteristics:

Both the new and the predicate devices use the Laser Doppler imaging technology to visualize blood flow in the microcirculation. While the predicate devices perform a single point and a 1-dimensilonal line scan, respectively, the Aïmago EasyLDI performs a 2-dimensional area scan.

Summary of Testing:

Testing has been performed in-house as well as at contract laboratories has demonstrated that the Aïmago EasyLDI fulfills the requirements for Subpart B of Part 15 for Class A digital devices according to the FCC Rules for Digital Devices, the requirements ESD safety and electromagnetic immunity according to standard IEC 60601-1-2 and all electrical safety requirements from IEC 60601-1.

Conclusion:

Based on the above, Aïmago SA concluded that the Aïmago EasyLDI microcirculation camera is substantially equivalent to the legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aimago SA
% Mr. Marc Andre'
Chief Technology Officer
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Lausanne, Switzerland 1015

AUG 10 2012

Re: 121429
Trade/Device Name: EasyLDI Microcirculation Camera
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: July 17, 2012
Received: July 19, 2012

Dear Mr. Andre':

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121429

Device Name: EasyLDI Microcirculation Camera

Indications for Use:

The Aïmago EasyLDI Microcirculation Camera is intended for blood flow measurements in the microcirculation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121429